Rapid Assessment of Antimalarial Drug Availability and Use in Nigeria, February–March 2004

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ACRONYMS

ACT	artemisinin-based combination therapy
AFRO	Regional Office for Africa [World Health Organization]
AIDS	acquired immune deficiency syndrome
CDC	U.S. Centers for Disease Control and Prevention
CIF	cost, insurance, freight
CQ	chloroquine
DAS	Drug Availability Study
DMA	Drugs Management Agency
DMM	Drug Management for Malaria
DTET	Drug Trial and Efficacy Testing
DUS	Drug Use Study
EDL	Essential Drugs List
EDP	Essential Drugs Program
FEFO	first expiry, first out
FIFO	first in, first out
FMOH	Federal Ministry of Health
FOB	free on board
GFATM	Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
HIV	human immunodeficiency virus
IEC	information, education, communication
IP	implementing partner
IPT	intermittent preventive treatment
ITN	insecticide-treated net
LGA	Local Government Area
MAC	Malaria Action Coalition
MIP	median international price
MNH	Maternal and Neonatal Health
MOH	Ministry of Health
MSH	Management Sciences for Health
NAFDAC	National Agency for Food and Drug Administration and Control
NHIS	National Health Insurance Scheme
NMCP	National Malaria Control Program

PCN	Pharmacists Council of Nigeria
PHC	Primary Health Care
PMU	Pharmaceutical Manufacturing Unit
RBM	Roll Back Malaria
RPM Plus	Rational Pharmaceutical Management Plus [Program]
SP	sulfadoxine-pyrimethamine
STGs	standard treatment guidelines
USAID	U.S. Agency for International Development
USD	U.S. dollar
WHO	World Health Organization

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MAP OF NIGERIA SHOWING STATES AND FEDERAL CAPITAL TERRITORY

EXECUTIVE SUMMARY

Nigeria's National Antimalarial Treatment Policy,[1] dated 2001, recommends chloroquine (CQ) as the first-line medicine for treatment of malaria, while sulfadoxine-pyrimethamine (SP) is recommended as the second line or as an alternative when circumstances make the use of chloroquine inappropriate or impossible. Following Drug Therapy Efficacy Testing (DTET) studies aimed at determining the status of first- and second-line antimalarial medicines, consensus of stakeholders in Nigeria agreed that in the parts of Nigeria where the resistance to CQ and SP was found to be above 25 percent, an artemisinin-based combination therapy (ACT) should be promoted and that efficacy of antimalarials needs to be studied at least every two years.

A major pharmaceutical management challenge to the introduction of ACTs identified by in-country Roll Back Malaria (RBM) stakeholders is the complexity of pharmaceutical management systems in Nigeria. Using U.S. Agency for International Development (USAID)/Malaria Action Coalition (MAC) funds provided by the Nigeria Mission, the Rational Pharmaceutical Management Plus (RPM Plus) Program collaborated with the World Health Organization (WHO) Regional Office for Africa (AFRO) and RBM partners in Nigeria to assess the availability and use of antimalarials within the public and private sectors of Nigeria. It was agreed that this assessment was critical to identify any bottlenecks in the antimalarial pharmaceutical supply system and to identify appropriate points of intervention. The assessment would then propose interventions to address the identified problems prior to and during implementation of the new policy with an aim to ensure the availability and proper use of the selected ACT for the treatment of malaria.

The rapid assessment was based on the *Drug Management for Malaria (DMM) Manual*, an indicator-based assessment tool developed by the RPM project, in collaboration with USAID. The assessment—built around two complementary studies, a Drug Availability Study (DAS) and a Drug Use Study (DUS)—assessed various aspects of pharmaceutical management in the public and private sectors. The two-part assessment collected data from four different settings: federal level, state level, health facilities (Ministry of Health [MOH] and formal private sector facilities), and drug retail outlets within selected Local Government Areas (LGAs) in Nigeria. In addition, a literature search and review of relevant background documents was done.

The rapid assessment was conducted between March 1 and March 30, 2004. A total of 4 state medical stores, 22 health facilities, and 40 drug retail outlets were visited and investigated for the availability and use of malaria tracer drugs. Four teams comprising six data collectors in Cross River state and five data collectors in each of the three remaining study states (Borno, Kano, and Lagos) were responsible for data collection. Each team had one state RBM program manager, two pharmacists, and a member of the Federal Ministry of Health (FMOH) RBM unit acting as team leader.

[1] The policy is currently being revised and is awaiting presentation to the National Council of Health.

This rapid assessment highlights some challenges in the Nigeria's pharmaceutical management system and shows that all areas of the pharmaceutical management cycle need to be strengthened. The findings include the following—

1. Selection of medicines for use in malaria control in Nigeria is done at the federal level of government and incorporated into the National Essential Drug List (EDL) which the assessment found to be regularly updated to meet the needs of the majority of the country. Manufacturers, distributors, and facilities, both public and private, largely adhere to the medicines listed in the EDL. This is facilitated by the presence of efficient regulatory agencies in-country.

2. Procurement of antimalarial medicines is decentralized to the state, LGA, and facility levels. States have seemingly adopted procurement and distribution systems that serve to suit their particular requirements. However, the highly decentralized nature of procurement, even to the smallest facility level, is prejudiced by the individual desire for profits, with not much consideration given to the cost of medicines to the end-user. Cost of antimalarial medicines in most states is absorbed by the government through drug revolving fund schemes. Patients are charged only registration fees.

3. Antimalarials have limited availability, with better availability in the state medical stores and lower availability at the health facility level. At the health facilities surveyed, stock-outs of antimalarial medicines occurred.

4. Reference sources on appropriate diagnosing and prescribing practices, such as the standard treatment guidelines (STGs), were found to be absent in most facilities surveyed. In spite of this, health workers in facilities surveyed had adequate prescribing practices.

5. Private sector drug retail outlets are prescribing and dispensing nationally recommended treatments for malaria. The average costs of malaria treatment are higher in the private drug retail outlets. Patients receiving care from private facilities and retail outlets are more likely to be able to correctly describe antimalarial administration.

The functioning of an efficient pharmaceutical management system should result in the availability of appropriate antimalarials in adequate quantities all the time. This is currently not the case in Nigeria, and as such improvement is needed in the system to accommodate the implementation of an ACT policy. In summary, the key challenges observed by the rapid assessment might be said to include the following—

- Unconsolidated procurement of medicines
- Inadequate inventory and stock management
- Poor record-keeping in facilities
- Frequent stock-outs of antimalarial drugs

The findings of the rapid assessment presented in this report indicate specific problems in the availability and use of antimalarial medicines in Nigeria. The indicators presented in the report

should be viewed as the first step in a process of investigation of the problems discussed in the report. The findings are meant to help the RBM unit of the FMOH define the challenges that come with the implementation of the new ACT policy. These challenges should be discussed by key RBM stakeholders and stakeholders in the pharmaceutical sector with the aim of improving the system. This report can serve as an advocacy tool to prompt policy makers to write policies that improve the availability of affordable medicines.

The rapid nature of this assessment did not allow for in-depth determination of the challenges identified. It is therefore recommended that further investigation using more qualitative methods be used to determine reasons for the challenges identified.

Pharmaceutical management–specific recommendations to ensure the smooth implementation of the new ACT policy are listed below.

Federal Ministry of Health

- Evaluate further the pharmaceutical management system to determine best practices with respect to selection, procurement, distribution, and rational use of medicines, including antimalarials
- Guide public pharmaceutical management practice by stating and implementing policies that would lead to the effective selection, procurement, distribution, and rational use of medicines, including antimalarials
- Identify funding sources for procurement of artemether-lumefantrine to ensure that adequate quantities are made available
- Assess suppliers, both local and international, to ensure increased availability of artemether-lumefantrine
- Attain competitive price for artemether-lumefantrine using the *International Drug Price Indicator Guide* published by Management Sciences for Health (MSH) in collaboration with the World Health Organization as a guide
- Enforce drug quality through continuous monitoring by National Agency for Food and Drug Administration and Control (NAFDAC), as the cost of artemether-lumefantrine will tend to encourage counterfeiting
- Make available standard, simple store management tools such as reporting forms, stock cards, and ledgers within federal, state, and LGA stores and at all levels of the primary health care (PHC) system

Roll Back Malaria Unit

- Advocate for bulk procurement of artemether-lumefantrine to ensure low purchase costs resulting in financial accessibility to the population
- Integrate the distribution of artemether-lumefantrine under the new policy into existing systems to ensure sustainability
- Ensure adequate production and wide dissemination of new treatment policy and standard treatment guidelines amongst relevant stakeholders and to health facilities in both the public and private sectors of Nigeria. The availability of these documents will give health workers assess to good reference material, enabling them to be conversant with the ACT regimens.
- Reinforce positive prescribing and dispensing behaviors by training and supporting providers, dispensers, and shopkeepers in both the public and private sectors
- Initiate training of relevant personnel in the medical stores and health facility stores at all levels of the PHC system to enable efficient pharmaceutical management of artemether-lumefantrine within the public sector. Training would include record-keeping, inventory, and store management.
- Undertake effective demand creation for the introduction of artemether-lumefantrine
- Continue to collaborate with managers of other sectors to ensure a coordinated approach to the delivery of effective malaria treatment and preventive measures by formal and informal practitioners

Pharmaceutical Sector Stakeholders

- Advocate for and provide technical assistance to the FMOH for the establishment of efficient pharmaceutical management systems
- Make available to the FMOH, federal medical stores, and LGA medical stores hard copies of the *International Drug Price Indicator Guide* published by MSH in collaboration with the World Health Organization for use as a reference
- Provide support for the training of relevant personnel in the medical stores and health facility stores at all levels of the PHC system to enable efficient pharmaceutical management within the public sector. Training would include record-keeping, inventory, and store management.
- Work with the RBM unit to investigate franchising and accreditation of drug retail outlets

Donors

- Treat pharmaceutical management as a high priority for public health in Nigeria and therefore provide support to the FMOH for activities aimed at strengthening the system

INTRODUCTION

Background

Nigeria lies on the west coast of Africa and has a surface area of 923,708 square kilometers and a population of about 118,000,000 (projected from the 1991 census). The country is divided into six geopolitical zones: North West, North East, North Central, South West, South East, and South South. It has 36 states plus the Federal Capital Territory. The states are further divided into 774 LGAs. The three tiers of government are federal, state, and local governments.

Malaria is endemic in Nigeria, accounting for the majority of outpatients seen in all age groups at the health facilities. The disease is a major cause of morbidity and mortality, accounting for 25 percent of infant mortality and 30 percent of childhood mortality (Ejezie, 1990). A minimum of 50 percent of the population suffer from at least one episode of malaria each year. Given Nigeria's total population, this translates to 59 million people suffering from attacks of malaria yearly. It is the most common cause of outpatient attendance in all age groups and the most common cause of mortality in children under the age of five years (NMCP, 1996). Transmission of malaria is stable in all parts of the country, with high intensities in the northern part of the country during the short wet season as compared with low transmission during the long dry season. In the southern part of the country, transmission is intense, stable, and uniform throughout the year. There is also a difference in disease transmission rate between rural areas, where the disease is holo-endemic, and urban areas, where the disease is meso-endemic.

Nigeria, like most malaria-endemic countries, has had a long history in malaria control dating back to its independence era. However, in the last five years, advocacy, political awareness, and commitment to malaria control have continued to improve. In 1987, Nigeria developed its first National Malaria Control Policy. In 1996, the implementation of the malaria policy was accompanied by Plans of Action for malaria control; revitalization/re-establishment of malaria control units in the states; advocacy for increased funding for malaria control; and resuscitation of national malaria technical committees and training activities.

Recent malaria control efforts are based on the principles of the WHO RBM Initiative, which was launched in September 1998. Nigeria re-affirmed its commitment to the initiative by hosting and co-financing the African Heads of State Summit on Roll Back Malaria in Abuja in April 2000. Among many other African leaders, Nigeria made a commitment at the summit to intensify efforts to ensure that by the year 2005—

- At least 60 percent of those suffering from malaria have prompt access to and are able to use correct, affordable, and appropriate treatment within 24 hours of the onset of symptoms

- At least 60 percent of those at risk of malaria, particularly pregnant women and children under five years of age, benefit from the most suitable combination of personal protective measures such as insecticide-treated nets (ITNs) and other interventions that are accessible and affordable to prevent infection and suffering

- At least 60 percent of all pregnant women who are at risk of malaria, especially those in their first pregnancies, have access to chemoprophylaxis or intermittent preventive treatment (IPT)

A major intervention for malaria control proposed by Roll Back Malaria is the provision of effective, affordable, acceptable, and available antimalarial medicines to enhance prompt and effective treatment of malaria episodes within 24 hours of onset of illness. Nigeria's National Antimalarial Treatment Policy,[2] dated 2001 (FMOH/NMVCP, 2001b), recommends chloroquine as the first-line medicine for treatment of malaria, while SP is recommended as the second line or as an alternative when circumstances make the use of chloroquine inappropriate or impossible.

However, the emergence of fast-spreading parasite resistance to these affordable and available antimalarial medicines in many countries, including Nigeria, has called for the continual evaluation of the efficacy of these medicines, which is expected to inform decisions on malaria treatment policy issues.

At the time of 2001 revision of the policy, parasite resistance to chloroquine was determined to be widespread but varied in intensity from one part of the country to another. In some parts of the southwest, resistance was up to 15–20 percent in vitro and in vivo, and up to 30–50 percent in vivo in some parts of the southeast. However, resistance in most cases was classified as mild, and the response in vivo to chloroquine was determined to be still encouraging. At the time, there was also evidence of diminishing sensitivity in vivo of the parasite to SP in some areas of the country. In some parts of the southwest, resistance to SP was found to be up to 10 percent.

Since 2001, Nigeria has been undertaking Drug Therapy Efficacy Testing studies aimed at determining the status of first- and second-line antimalarial medicines (FMOH, 2002). In December 2003, Nigeria released the technical report of its DTET studies, which have revealed that there is sufficient drug resistance to both chloroquine and SP in some parts of Nigeria to warrant a change in antimalarial treatment policy. Participants at a DTET consensus-building meeting held the same month in Nigeria agreed that in those parts of Nigeria where the resistance to CQ and SP is above 25 percent, an artemisinin-based combination therapy should be promoted and that efficacy of antimalarials needs to be studied at least every two years.

In 2002, the USAID/Nigeria Mission provided funds to the Malaria Action Coalition, a four-member partnership developed under the direction of USAID/Washington to address gaps in technical support for two major RBM intervention areas: malaria in pregnancy and appropriate case management. The partners are WHO/AFRO, the U.S. Centers for Disease Control and Prevention (CDC), MSH/RPM Plus, and the ACCESS Program of Johns Hopkins University (formerly Maternal and Neonatal Health [MNH]). USAID/Nigeria at the time was supporting malaria intervention and research through six implementing partners (IPs), and it was anticipated that MAC technical assistance would not only assist the USAID Nigeria IPs but would also aid the other RBM partners and the Government of Nigeria. To that end, MAC conducted a situational analysis in Nigeria between April and September 2003, after which representatives of the four MAC partners met in Abuja in October 2003 and developed a two-pronged action plan and budget that focused 1) on helping Nigeria make the transition to a new antimalarial treatment

[2] This has currently being revised and is awaiting presentation to the National Council of Health.

policy involving the use of ACTs and 2) on stimulating the development and dissemination of clear policy and management guidelines for malaria in pregnancy.

Justification for the Rapid Assessment

During the October 2003 MAC planning meeting with the RBM unit of the FMOH, the complexity of pharmaceutical management systems in Nigeria was identified by in-country RBM stakeholders as a major challenge to the introduction of ACTs. Also discussed was the enormous role of the private sector medicine sellers, how they operate, and how to manage their involvement in implementing an ACT policy so as to ensure access to nationally recommended antimalarials. A decision was taken to incorporate the investigation of these issues as an activity within the MAC joint workplan.

Using USAID/MAC funds provided by the Nigeria Mission, RPM Plus collaborated with the WHO/AFRO and RBM partners in Nigeria to assess the availability and use of antimalarials within the public and private sectors of Nigeria. It was agreed that this assessment was critical to identify any bottlenecks in the antimalarial pharmaceutical supply system and identify appropriate points of intervention. The assessment would then propose interventions to address the identified problems prior to and during implementation of the new policy, with an aim to ensure the availability and proper use of the selected ACT for the treatment of malaria.

METHODOLOGY

Assessment Methodology

The rapid assessment was based on the *Drug Management for Malaria (DMM) Manual*, an indicator-based assessment tool developed by the RPM Project in collaboration USAID (Clark, 2000). The *DMM Manual* is designed to guide the review of drug availability and patterns of use of drugs for malaria treatment in public health facilities of the MOH and in private facilities, pharmacies, and drug retail outlets. Such reviews help to diagnose existing or emergent problems in malaria drug management and provide the evidence required for making decisions on how to improve access to, as well as the use of, antimalarial drugs in both the public and private sectors.

The assessment was built around two complementary studies: a Drug Availability Study and a Drug Use Study. The two studies assess various aspects of pharmaceutical management in the public and private sectors.

Drug Availability Study

The purpose of conducting the DAS was to determine the degree to which the antimalarial medicines required for treating and preventing malaria are available. The DAS indicators are expected to help the FMOH RBM team identify possible reasons for the low availability of antimalarial medicines, as well as opportunities for improving the supply.

The three data collection techniques used for the DAS were document reviews, structured interviews, and physical inventory checks.

Drug Use Study

The purpose of conducting the DUS was to review prescribing and dispensing practices for malaria and to assess their clinical and cost implications. The drug use information obtained would be expected to guide the involvement of prescribers in the drug policy change and to target specific behaviors through training and subsequent monitoring and supervisory activities.

The DUS used both retrospective and prospective methods. For the retrospective component of the study, the data collection technique used was medical records review in MOH and formal private sector facilities. The prospective component used the techniques of direct observation and exit poll interviews in MOH and formal private sector facilities and simulated purchases in drug retail outlets.

DMM Indicators

Twelve DMM indicators were used to assess the availability and use of antimalarial drugs for the treatment of malaria in the public and private sectors of Nigeria. The indicators include four availability indicators, six drug use indicators, one observation indicator, and one IPT indicator.

Drug Availability Study Indicators

An accurate and systematic assessment of the drug supply system is a prerequisite for planning improvements to the malaria drug supply system. The DAS indicators (1 through 4 shown below) focus on procurement and distribution of antimalarials.

1. Percentage of median international price paid for a set of DMM antimalarial drugs that were part of the last regular MOH procurement

2. Average percentage of a set of unexpired DMM antimalarial drugs available in (a) MOH storage and health facilities, (b) retail drug outlets, and (c) formal private health facilities

3. Average percentage of time out of stock for a set of DMM antimalarial drugs in MOH storage and health facilities

4. Average percentage of stock records that correspond with physical counts for a set of DMM antimalarial drugs in MOH storage and health facilities

Drug Use Study Indicators

The DUS indicators (5 through 12 below) focus on current drug use practices in the health system for treating malaria. Nigeria has developed policies and treatment guidelines for malaria; however, as in most developing countries, despite years of promotion, health care providers frequently do not follow these guidelines when prescribing drugs. Whatever the intervention attempted in response to this problem, four needs are constant: identification of the specific prescribing behaviors to change, interventions to bring about positive change, assessment of the extent to which change takes place, and periodic monitoring of the status of problem behaviors.

5. Percentage of MOH health facilities visited that had a copy of the official treatment guidelines for malaria

6. Percentage of encounters with patients diagnosed with uncomplicated malaria in which they are prescribed an antimalarial consistent with treatment guidelines (public and private health facilities)

7. Percentage of encounters with patients diagnosed with uncomplicated malaria in which they are prescribed quantities of appropriate antimalarials sufficient to complete a full course of treatment (public and private health facilities)

8. Percentage of prescribed antimalarial drugs actually dispensed by public health facilities

9. Average cost of drugs prescribed as a percentage of costs if STG norms for treatment are followed

10. Percentage of patients/caregivers who could correctly describe how to take/give the prescribed antimalarial medication

11. Percentage of health workers and drug retail outlets that provided [some] information to patients/caregivers on how to give the recommended drug(s)

12. Percentage of encounters with pregnant women living in malaria-endemic areas who are prescribed an appropriate antimalarial for IPT at antenatal clinics[3]

Selection of Data Collection Sites

In order to conduct the DAS and DUS, data was collected at the federal, state, and health facility levels. In addition, a literature search and review of relevant background documents were done.

Federal-level data collection was conducted through the process of document reviews and interviews at the Food and Drug Services department, the National Malaria Control Program (NMCP), the WHO office in Abuja, the federal medical stores, and the Federal Pharmaceutical Manufacturing Unit in Lagos.

The process of selection of state data collection sites was done in a tiered manner, starting with selection of states, then LGAs and health facilities, and finally drug retail outlets.

Four out of the 36 states in Nigeria were purposively selected for the rapid assessment. Two states where the DTET survey was conducted—Borno in Northern Nigeria and Cross River in Southern Nigeria—were sampled. Two other states, Kano and Lagos, were chosen primarily because they are the most populous in the North and South, respectively.

Within the four selected states, one LGA was selected for the rapid assessment. LGA selection was also purposive. Two of the four LGA selections were based on the fact that the DTET survey took place there. The other two were chosen from the LGAs that had at least one hospital and that were located close to the state capitals to minimize the logistic challenges of getting to the study sites. Initially selected DTET LGAs in Borno and Cross River states (Akampka and Damboa, respectively) had to be changed due to their geographic inaccessibility and some security concerns regarding traveling to the LGAs in Borno. Therefore, not all of the LGAs selected had had the DTET survey conducted there; instead, they were LGAs close to the state capitals.

The LGAs selected in the four states are listed in Table 1 below.

[3] This indicator is relevant in Nigeria because the country is implementing a policy recommending the provision of intermittent preventive treatment using SP.

Table 1. LGAs Sampled for the Rapid Assessment in Each State

State	Local Government Authority
Borno	Maidaguri Municipal
Cross River	Akpabuyo
Kano	Nassarawa
Lagos	Lagos Island

To select health facilities within sampled LGAs, stratified random sampling methods were used. The 2001[4] Federal Register of Health Facilities provided the sampling framework. This register lists all registered health facilities within each state and LGA by type (i.e., primary health care versus secondary care facilities). The register also indicates whether the facilities are public or privately owned facilities.

In sampling the health facilities within an LGA, the first level in stratified sampling methodology was based on the type of facility as listed in the register (i.e., the primary health care versus secondary facilities). From within these strata, a study sample was selected that included at least one hospital (secondary facility) and four health centers[5] (primary facilities). The facilities were randomly selected using the random number generator function in Microsoft Excel. For each LGA, backup facilities were also selected through similar processes prior to the start of fieldwork. In reality, however, most of the selected primary care facilities (including some backup facilities) were non-functional/closed or non-existent and had to be replaced with the nearest functioning health facility, which often was a secondary-level facility. Some randomly selected secondary care facilities were also non-functional and had to be replaced with the nearest functioning one.

Two drug retail outlets that were close to each selected health facility were selected for the assessment.[6]

The health facilities, including the number of drug retail outlets in each state that were sampled for the survey, are listed below.

[4] This was the most recent version of the register available.

[5] The definition of a health center, health post, and dispensary was not consistent across the different states. In some states, all the primary health facilities were called health centers, so these states had no health posts or dispensaries. In other states, health posts and dispensaries were recognized as distinct from health centers. To obtain some consistency, the assessment used the former definition of health center.

[6] In the absence of a list of the drug retail outlets in a particular LGA, data collectors were asked to select drug retail outlets by exiting a sampled health facility, turning right and walking to the nearest drug retail outlet.

Cross River State
Akpabuyo LGA
General Hospital, Calabar
General Hospital, Akamkpa
St. Josephs Hospital, Ikot Omim
Polyclinic (Health Center), Odukpani
Health Post, Akansonko
10 drug retail outlets (5 pharmacies and 5 patent medicine vendors)

Borno State
Maiduguri Municipal LGA
General Hospital, Molai
State Specialist Hospital, Maiduguri
Nursing Home Hospital, Maisandari
Comprehensive Health Center, Gwange
Comprehensive Health Center, Bolari
Nakowa Private Hospital and Maternity, Nakowa
10 drug retail outlets (4 pharmacies and 6 patent medicine vendors)

Lagos State
Lagos Island LGA
Lagos Island General Hospital
Massey Street Children's Hospital
General Hospital, Gbagada
Onikan Health Center
Lagos Island Maternity Hospital, Health Section
Adeniji Adele PHC facility
10 drug retail outlets (6 pharmacies and 4 patent medicine vendors)

Kano State
Nassarawa LGA
Sir Mohammed Sunusi General Hospital
Murtala Mohammed Specialist Hospital
Tudun Wada General Hospital
Gwagwarwa family clinic
Kawaji Government Secondary School Clinic
10 drug retail outlets (2 pharmacies and 8 patent medicine vendors)

Data Collection

Preparation Phase

Data collection tools were adopted from the *DMM Manual* and adapted to some extent prior to the assessment. The adaptation process involved the removal of some columns in some of the tools to prevent the confusion that most of the data collectors had in trying to understand and use

the tools during the field test that was conducted as part of the training. At the beginning of the assessment, RPM Plus personnel worked with a consultant to oversee training and preparation for the data collection.

During the preparatory phase, the team coordinated with RBM stakeholders in Nigeria, including the NMCP coordinator and the WHO National Professional Officers for malaria. An intensive preparation phase was carried out that entailed discussions amongst partners on the objectives of the study, collection of background documents, arrangement of logistics, and discussion and adaptation of the assessment tools to suit the Nigerian context.

Development of Tracer List

A list of antimalarial drugs, their strengths, and their forms was drawn up. This tracer list is listed in Table 2.

Table 2. Antimalarial Tracer List for Nigeria Rapid Assessment

Antimalarial	Strength	Form
Amodiaquine	200 mg	Tablet
Artemether-lumefantrine	20 mg/120 mg	Tablet
Artemether injection	80 mg/mL in 1 mL	Ampoule
Artesunate	50 mg	Tablet
Artesunate	200 mg	Rectocap
Chloroquine	50 mg	Tablet
Chloroquine	75 mg	Tablet
Chloroquine	150 mg	Tablet
Chloroquine	150 mg	Caplet
Chloroquine	300 mg	Capsule
Chloroquine	300 mg	Tablet
Chloroquine	50 mg/5 mL	Syrup
Chloroquine injection	40 mg/mL in 5 mL	Ampoule
Dihydroartemisinin	80 mg	Tablet
Halofantrine	250 mg	Tablet
Mefloquine	250 mg	Tablet
Mefloquine/sulfadoxine-pyrimethamine	250 mg/500 mg–25 mg	Tablet
Proguanil hydrochloride	100 mg	Tablet
Pyrimethamine	25 mg	Tablet
Quinine	300 mg	Tablet
Quinine injection	300 mg/mL in 2 mL	Ampoule
Sulfadoxine-pyrimethamine	500 mg/25 mg in 2.5 mL	Ampoule
Sulfadoxine-pyrimethamine	500 mg/25 mg in 5 mL	Syrup
Sulfadoxine-pyrimethamine	500 mg/25 mg	Tablet

The tracer list was developed by consensus (NMCP coordinator, data collection team leaders, consultant, and RPM Plus staff) and was a composite of antimalarial drugs on the most recent editions of the National EDL (FMOH, 2003) and the federal STGs for malaria (FMOH/NMVCP, 2001a). The consensus was that this same tracer list should be used for investigation at the following levels of the pharmaceutical management distribution system—

- Federal medical stores/state medical stores
- General hospital/state hospital/tertiary hospital
- Health center
- Private pharmacy/drug retail outlet

The use of one tracer list for all the levels was agreed on because the assessment team did not have access to EDLs for sub-federal-level entities and facilities. Because of this lack of access, it was not possible to develop level-specific tracer lists because there was no consensus on what medicines were routinely carried in the different levels of the health care system. In future assessments, this tracer list may need to be revised to target different levels of the health care system.

Training

The data collectors for the assessment were drawn from the federal and state levels. For logistical reasons, it was decided to conduct two training sessions. Two data collectors for each state were recruited from the RBM unit of the FMOH in Abuja. Training of this group of data collectors was done at the central level at the offices of the FMOH RBM Secretariat in Abuja, Nigeria. The training was done over a two-day period and included a field test of the data collection tools that was done on the second day of training. Feedback from this field test was used to further adapt the tools.

At the end of this first training session, a team leader for each data collection team was selected based on their performance during the training session. This team leader was responsible for conducting the training of the data collectors who would be drawn from the state level and for the actual data collection process in the states.

A briefing session was held with team leaders prior to the departure for the states to discuss the training of the additional data collectors, study sites, study logistics, and contact information. The four teams were provided with the tools they would use for the training and data collection and then departed for the four selected states in Nigeria.

Training of the data collectors drawn from the states was done over a two-day period when team leaders arrived in their respective states. The training was followed by a field test before actual data collection in the field was begun.

Data Collection

Data collection was conducted over a two-week period, March 15–26, 2004. Four teams comprising six data collectors in Cross River state and five data collectors in each of the three

remaining selected states were responsible for data collection. Each team had two members from the FMOH RBM unit, one of whom was the team leader[7]; the state RBM program manager; and two state pharmacists drawn from the states assessed.

The final data collection tools were adopted after a process of scrutiny, pretesting, and revision in collaboration with the FMOH RBM Secretariat. Thirteen sets of data collection tools were used in the assessment (Table 3).

Table 3. Forms Used and Types of Personnel Interviewed at Health Facilities

	Form	*Personnel Interviewed*	*Number of Encounters*
Inventory data forms – Health centers	***DAS-2B***	Dispenser/Pharmacist	N/A
Inventory data forms – Hospitals	***DAS-2C***		
Inventory data forms – Medical stores	***DAS-2D***	Manager/Pharmacist-in-Charge	N/A
Inventory data forms – Drug retail outlets	***DAS-2E***	Dispenser/Pharmacist	N/A
Stock-out data form – Health centers	***DAS-3B***	Dispenser/Pharmacist/Storekeeper	N/A
Stock-out data form – Hospitals	***DAS-3C***		
Stock-out data form – Medical stores	***DAS-3D***	Manager/Pharmacist-in-Charge	N/A
International Price Comparison form	***DAS-4***	Manager/Pharmacist-in-Charge	N/A
Medical Records Review form – Simple malaria	***DUS-1A***	Medical Records Officer/Nurse	30 per facility
Medical Records Review form – Pregnant Women	***DUS-1B***	Medical Records Officer/Nurse	10 per facility
Observation of Health Worker form	***DUS-2***	Facility Supervisor	10–15 per facility
Patient/Caregiver Exit Interview form	***DUS-3***	Facility Supervisor	10–15 per facility
Simulated Purchase form	***DUS-4***	N/A	20

Note: N/A = not applicable.

Data Collation and Management

Data was edited and entered into a Microsoft Excel spreadsheet over a one-week period at the MSH regional office in Nairobi, Kenya. Data analysis was done using Excel. Due to a delay in the start of the assessment and hence time constraints, training of team leaders focused only on data collection and did not include training on data analysis. Some field data analysis would have been ideal in order to build capacity for subsequent use of the assessment methodology in-country. Indicator values were calculated, and information on pharmaceutical management operations at the federal and state levels was compiled.

[7] The exception was Cross River state, where the team was led by the WHO/EDM National Professional Officer.

QUALITATIVE INFORMATION ON MALARIA AND THE PHARMACEUTICAL SECTOR

General Description of the Health Sector in Nigeria

Structure of the Public Health System

All tiers of the government—federal, state, and local—share the responsibility of providing health services and programs in Nigeria (FMOH/WHO, 2002). The federal government is principally in charge of providing policy direction, planning, and technical assistance; managing state-level implementation of the National Health Policy; and instituting health management information systems. Additionally, the federal government is responsible for disease surveillance, drug regulation, vaccine management, and training of health professionals. The management of teaching, psychiatric, and orthopedic hospitals as well as some medical centers lies within the mandate of the federal government.

The main strategy adopted in Nigeria since 1988 has been the primary health care approach with emphasis on equity and social justice. The health care system aims to provide a health system in which communities can participate in the planning and delivery of health services. The health care system consists of three levels of health care services, namely, primary, secondary, and tertiary.

The responsibility for administration of health facilities and programs is shared by the State MOHs, State Hospital Management Boards, and LGAs. The states manage the secondary health facilities (general hospitals) and in some cases tertiary hospitals as well as some primary health care facilities. In addition, the states are responsible for training of some categories of medical staff and for the provision of technical assistance to local government health programs and facilities.

The 774 local governments oversee the operations of PHC facilities within their geographic areas. These operations include basic health services, community health hygiene, and sanitation.

Due to insufficiencies in the functioning of the Nigeria public health system, the private health sector (profit and nonprofit) facilities and traditional and spiritual healers are largely relied upon.

Malaria Control

The Government of Nigeria is committed to the principles of the RBM Initiative (FMOH, 2001). At the federal level in Nigeria, the National Malaria Control Program has competent staff. All states and LGAs also have Malaria Control Program units with focal persons in place in a decentralized manner for effective implementation of malaria policies, guidelines, and activities. Health services system reform is ongoing in the country, which also aims to enhance the effective implementation of any malaria policies.

The five strategic approaches of RBM in Nigeria include—

- Disease management
- Multiple prevention measures (chemoprophylaxis, use of ITNs, and environmental management)
- Information, education, and communication (IEC) and social mobilization
- Operational research
- Partnership

The RBM Initiative has an existing public-private sector partnership jointly responsible for funding, implementation, demand creation, and monitoring and evaluation with respect to malaria activities. The program adopts a multisectoral approach in all its implementation strategies in order to create a synergized convergence of efforts. This approach involves the ministries of Agriculture, Environment, Women's Affairs and Youth Development, Information, Industries, Works, and Housing, as well as the oil-producing sector among others and is seen as beneficial to implementation of policies. Malaria program implementation is also guided by the following existing policies: the National Health Policy, National Malaria Control Policy, Strategic Plan, Antimalarial Treatment Policy, and ITN Policy.

Nigeria submitted and was approved funding of USD 17,828,808 for its Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) Round II malaria proposal. The proposal is for a five-year project spanning 12 states in Nigeria and covering a population of 4.4 million children under the age of five and 870,000 pregnant women (Nigeria has a total population of 107.5 million). The objective of the proposal is to reduce malaria mortality and morbidity in children under five and pregnant women by 30 percent by the year 2007, through—

- Increasing coverage with insecticide-treated nets for pregnant women and children under five years from 5 to 55 percent by 2007
- Increase the proportion of children under five correctly treated for malaria using pre-packaged drugs from 12 percent to 60 percent by 2007
- Increase the proportion of women who use SP IPT from 0 percent to 50 percent by 2007, mainly through training of health personnel in IPT

In addition, Nigeria applied for and has received approval for GFATM Round IV funds for implementation of the proposed new ACT policy (GFATM, 2002).

Background Information on Pharmaceutical Sector Operations

The key functions of Nigeria's pharmaceutical supply system can be classified as selection, procurement, distribution, and use. The ideal functioning of such functions should be as shown in Figure 1 and should be supported by skilled general management, effective organization, and adequate financial and human resources.

SELECTION
Drug Formulary Systems
Regional Formularies
Antimicrobial Resistance
Drug Utilization Review
ABC/VEN Analysis
Pharmacoeconomics
STG-based Drug Selection

USE
Drug Information Development
Rational Prescribing
Antimicrobial Resistance
Good Dispensing Practices
Drug Utilization Review
Standard Treatment Guidelines
Formulary Manuals
Patient Information/Counseling
Curriculum Reform
Medical Literature Review
Drug Use Intervention Research

DISTRIBUTION
Processing Import Documents
Warehouse Management
Kits/Stores Inventory Control
Kit Systems

POLICY AND LEGAL FRAMEWORK
Drugs of Choice
Drug Registration
Procurement Laws
Generics Policies
Accreditation/Licensing (Hospitals, Pharmacies)
Pharmacopeial Standards
Decentralization Decisions
Prescription Drug Availability
Privatization
Contracting Out
Integration of Services/Supply Systems

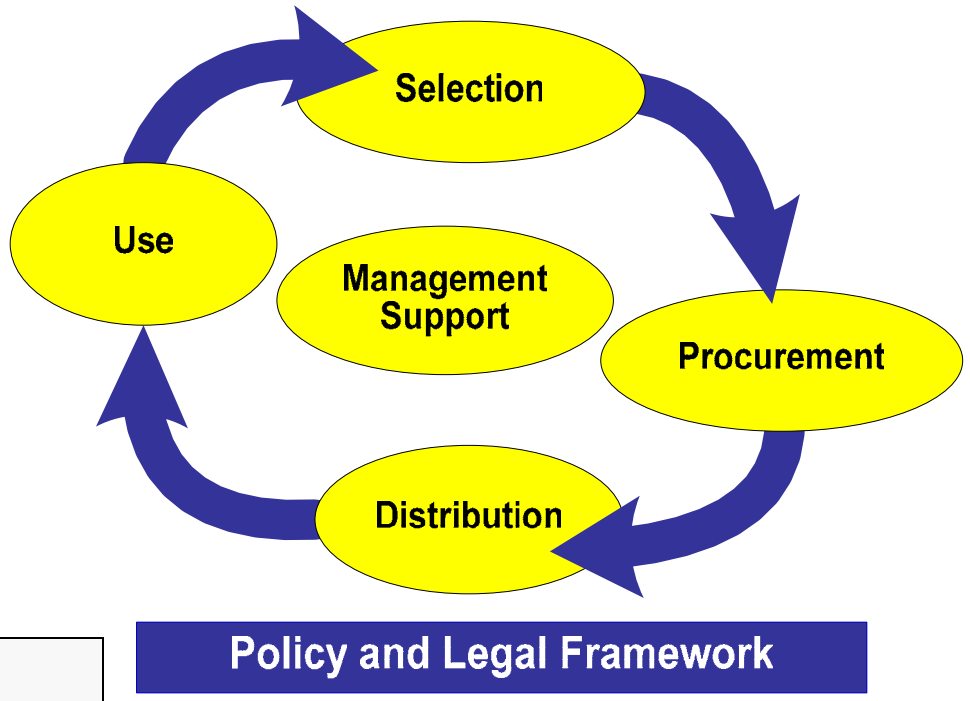

Figure 1. The key functions of an ideal pharmaceutical supply system

MANAGEMENT SUPPORT
Organization
Vertical Programs
Integration
Decentralization
Contracting Out
IMCI
Financing
Budgeting/Expenditures
Cost Recovery/User Fees
Cost Containment
Reproductive Health Costing
Health Insurance
DRGs/Managed Care
Donor Financing/Loans
Pharmacy Benefits Management
Information Management
Indicators
Morbidity Information
Surveillance Information
Consumption Data
Procurement Data
LMIS
Human Resources
Preservice Education
Continuing Education
In-service Training
District-Level Management
DDM

PROCUREMENT
ABC/VEN Analysis
STG-based Quantification
(Morbidity/Consumption Info)
Tendering/Adjudication
Specifications/Contracts
Pooled Purchases
Buying Groups
Lead-Time Analysis
Supplier Monitoring
Access to Supplier/Price Info
Prequalification of Suppliers
Donor Coordination
Drug Donation Guidelines

Policy and Legal Framework

The National Drug Policy

Nigeria's National Drug Policy was first published in 1990 with the aim of making adequate supplies of effective, affordable, safe, and good-quality drugs available at all times and in all sectors of the health care system. The policy is also aimed at improving the quality of health care through the rational use of drugs.

To date, the policy in place does not appear to have made significant impact on the pharmaceutical sector largely due to the absence of an implementation plan, budget, and timelines. At the time of the assessment, the policy was being revised with efforts being made to improve on the formulation process and to include an implementation plan. It is envisaged that the revised policy will be disseminated widely to ensure the support and commitment of stakeholders as well as the systematic implementation of the policy.

The Essential Drugs List

Nigeria's EDL was first published in 1986. The adoption of the EDL is a key strategy in Nigeria for achievement of one of the goals of the National Drug Policy: to make available at all times, in adequate dosage forms, drugs needed within the health care system. The current edition of the list (2003) is the fourth revision. Although the EDL includes drugs for the primary health care level, the list for the PHC level is published as a separate document. The assessment found that while some states have adapted the national EDL to their local needs, other states, including Borno, Cross River, Kano, and Lagos, use only the national EDL.

Legislation

The regulation of the pharmaceutical sector is directed by NAFDAC and the Pharmacists Council of Nigeria (PCN). NAFDAC regulates pharmaceutical products while the PCN regulates pharmaceutical premises and professional practice.

National Agency for Food and Drugs Administration and Control

NAFDAC's mission is to safeguard public health by ensuring that good-quality, safe, regulated products are circulated in Nigeria. The agency fulfils its mission by controlling drug registration, marketing approval, manufacturing, importation, and drug promotion and advertising.

NAFDAC issues marketing approval for pharmaceuticals sold in Nigeria only after evaluation of safety, efficacy, and the proof of manufacturing and use in country of origin. With support from the World Health Organization, NAFDAC currently has a computerized system for the registration of drugs. At present, the use of a registration number on all registered drugs is mandated. Currently, almost 4,500 medicines are registered in the country, with about 83 of these being traditional medicines with proof of safety. The register also includes products not on the EDL but with demonstrated efficacy. The agency regularly publishes the list of registered drugs in the official gazette.

NAFDAC's other activities include—

- *Regular inspection of drug manufacturing premises.* Inspection is done locally and abroad to ensure manufacturer compliance with Good Manufacturing Practices (GMP). Locally, GMP certificates cover only two years, after which a reassessment and recertification of the manufacturer is required.

- *Regulation of promotion and advertisements of medicines*. Promotion and advertisement of pharmaceuticals is limited to over-the-counter drugs. The contents of advertisements and promotional materials and of package inserts are pre-approved by NAFDAC. Prescription-only medicines cannot be promoted nor advertised in Nigeria.

- *Collection of information of adverse effects of both orthodox and traditional medicines.* NAFDAC does not have the mandate to monitor adverse effects of drugs (pharmacovigilance); however, the agency collects secondary information on adverse drug reactions from bodies that are responsible for pharmacovigilance in the country.

- *Quality control of medicines.* NAFDAC has national agencies that monitor the quality of medicines. These agencies are based in Maiduguri, Lagos, Kano, Yaba, and Port Harcourt. Drugs are tested in laboratories at these agencies and in academic institutions for quality before registration.

- *Postmarket surveillance.* This surveillance is done routinely by the agency.

- *Enforcement.* NAFDAC is responsible for the enforcement of all laws and regulations governing pharmaceuticals in Nigeria.

There is no legislation regarding generic prescriptions in Nigeria, and dispensers are allowed to substitute generic drugs in the public sector. There is also no pricing policy for pharmaceuticals in Nigeria, but there is a 5 percent tax on pharmaceutical raw materials, and taxes range from 20 to 25 percent on finished pharmaceutical products.

Pharmacists Council of Nigeria

The PCN was set up in 1991 and was initially referred to as the Pharmacists Board of Nigeria. The council is responsible for the licensing of all pharmacists in Nigeria, the registration and regulation of all pharmaceutical premises, and the regulation of the professional practices at pharmacies. As such, activities under the PCN include—

- Registration
- Inspection of pharmaceutical premises
- Accreditation of colleges of pharmacy within Nigerian Universities
- Accreditation of all Nigerian schools of technology

The effective regulation of traditional medicines remains a challenge for the pharmaceutical sector.

Management Support

Financing of Medicines

The Federal Ministry of Health usually budgets for health services while individual health institutions at the secondary and tertiary levels spend on medicines chosen by the head of the institution. At the PHC level, the local government authorities budget for medicines. The FMOH is currently in the process of creating a national health account to enable the disaggregating of data on health expenditure.

In most states in Nigeria, patients attending public health facilities pay for their medicines through drug revolving fund schemes. Health facilities therefore charge only registration fees to patients, and revenue accruing from fees would have sustained these revolving funds; however, schemes have failed because the funds were used to meet other needs of the health facilities. Very few states provide free medicines to patients, but the assessment found that Lagos provides free malaria medicines to children under five.

Nigeria has recently launched a National Health Insurance Scheme (NHIS), which targets workers in establishments with more than 10 employees. A voluntary health insurance scheme is advocated for workers outside of the NHIS-specified category.

Drug donations are common in Nigeria, and although the country aims to utilize the donated drugs efficiently, there are no national guidelines on drug donations.

Procurement and Distribution

Pharmaceutical Production

Nigeria can be said to have one of the most well-developed pharmaceutical industries in sub-Saharan Africa. The country boasts approximately 200 local pharmaceutical manufacturers. The majority of these industries are privately owned; however, five are owned by the federal or state governments or their agencies.

Pharmaceutical Manufacturing Unit of the Federal Ministry of Health

The FMOH houses a Pharmaceutical Manufacturing Unit (PMU) under its Food and Drugs Services department. The unit was established in 1962 and at the time of its establishment received financial support from the Queen of England for its operations.

The unit functions by purchasing raw materials from overseas companies (using procurement agents such as Crown Agents), and the quality of these materials is assured and monitored. In the past, the unit produced a wide range of products, about 37 individual items; however, current production is limited to some antimalarials, paracetamol, folic acid, and more recently antiretrovirals on behalf of the FMOH. The PMU currently does not base its production on the

procurement cycle of its recipient institutions[8] (tertiary teaching and specialist health institutions, secondary health facilities, federal government secondary schools, unity schools, and the National Assembly). In the past, when federal procurement was centralized, production at the unit was based on the federal procurement plan.

Central Medical Store Operations

Operations at Federal Level

Medical stores can be found at the federal, state, and LGA levels in Nigeria. Historically, bulk procurement of pharmaceuticals was done centrally (federal level), with distribution of commodities being sent from the federal medical stores to state medical stores, which would in turn distribute to the LGAs and secondary-level health facilities. This bulk procurement function ceased in the late 1980s. Presently, each tertiary hospital has a purchasing committee that coordinates procurement as part of hospital services. Quantification of required drugs is typically not based on any scientific calculation, and stock-outs occur frequently within the public health system. The private sector health centers procure their own antimalarials.

The federal medical store is structurally and functionally under the Food and Drugs Services department of the Federal Ministry of Health. Currently, federal medical stores are reserved for storage of donated drugs, such as antiretroviral drugs for HIV patients and malaria drugs for program management. At the time of the rapid assessment, the only drug in the federal medical store was Cotexin (dihydroartemisinin), which had been donated by the Chinese government to the Government of Nigeria.

Operations at State Level

Each of the 36 states in Nigeria has and operates a state medical store. States have their own central procurement arrangements independent of the federal level. The assessment determined that these arrangements are not necessarily the same in the various states. A typical state-run store is supposed to stock all the drugs on the EDL and supply drugs to the public hospitals. However, frequent stock-outs in the stores have led to poorly stocked public health facilities.

Some local government agencies also have medical stores.

The distribution system for pharmaceuticals within the state public health sector is fragmented. It follows a somewhat centralized system, with the state stores at the central level distributing to LGA stores and secondary (general) hospital stores. PHC centers collect supplies from the LGA stores.

Borno State

The state central medical store (CMS) is responsible for the procurement and distribution of

[8] It is interesting to note that no purchases are made from the PMU by federal and state medical stores.

pharmaceuticals for state health facilities. There is some level of decentralization in the form of facility-based procurement; however, the MOH limits the procurement of these facilities. The CMS distributes pharmaceuticals to LGA medical stores, primary and secondary health care facilities, schools, army and police health facilities, and mobile ambulance services. Distribution to health facilities is based on a simultaneous "pull" and "push" system. One group of health facilities requesting pharmaceuticals are supplied these according to their needs, and the CMS pushes quantities of pharmaceuticals based on past consumption patterns to a second group of peripheral facilities on a monthly basis.

Major challenges identified include the need for training of medical stores' staff in inventory control, pharmacy management, and computer applications.

Cross River State

The Essential Drugs Program (EDP) of Cross River State is the body responsible for procurement of pharmaceuticals for all state health facilities. Procurement by the state government is jointly done with a private company, World Health Limited. State health facilities send a requisition form to the EDP, which in turn supplies pharmaceutical commodities as requested. In addition, the EDP supplies pharmaceuticals to the LGA medical stores, which in turn serve some of the primary health care facilities. Transport is borne by the receiving facility; however, the EDP makes available 5 percent of sales for transportation.

Major challenges include a shortage of store personnel and logistical challenges in distribution.

Kano State

The Kano State Drugs Management Agency (DMA) makes pharmaceutical commodities available at all government health facilities and LGA medical stores within the state. Cost recovery is achieved through a drug revolving fund. In addition, the DMA distributes pharmaceuticals to 65 drug retail outlets. The DMA has no major problems that affect the movement of pharmaceuticals through the procurement and distribution system.

The main need identified is the training of staff in information technology.

Lagos State

Procurement and distribution of pharmaceutical commodities in Lagos State is decentralized to the health facility level. Each facility's Drug Purchase Committee is given funds by the Ministry of Health. The state CMSs have structures (including inventory management software) and staff in place for the handling of donated items.

Major pharmaceutical supply challenges include inadequate funding, inventory, storage facilities, and transport. Major training needs of staff include inventory and stores management courses.

Table 3 shows a summary of the findings in the four states surveyed.

Table 3. Pharmaceutical Management Findings in Selected State Medical Stores

FINDING	STATE SURVEYED			
	Cross River	**Borno**	**Lagos**	**Kano**
		Procurement		
Procurement Committee in place	Yes	Yes	Yes	Yes
Written procurement plan	Yes	Yes	Yes	Yes
Ability to purchase all requirements	No (financial constraints)	No (limited funds; but all basic requirements are purchased)	No (inadequate funding)	Yes
Type of procurement	Centralized	Centralized	Decentralized to hospitals	Centralized
Possession of current EDL	Yes	Yes	Yes	Yes
		Quantification		
Methods used	Past consumption	Past consumption, morbidity, previous procurement quantities	Past consumption, previous procurement quantities	Past consumption, demand from pharmacy outlets in hospitals
Ultimate decision for procurement quantities and source	Procurement Committee and State Commissioner of Health	Drug revolving fund central committee	Director of Pharmacy Services (approval from procurement committee required)	General Manager and Director of Drugs
Problems with quantification	No	Lack of submission of timely data, poor availability of morbidity data	No, but funds are insufficient for quantities required	Dependent on availability of resources
Basis for selection of contract supplier	Winning bidder	Lowest price from prequalified supplier, lowest price of products deemed to be of acceptable quality	Lowest price of products deemed to be of acceptable quality	Lowest price of products deemed to be of acceptable quality
Responsibility for contract monitoring	Procurement Committee	Drug revolving fund monitoring committee	Store pharmacist	Director of Drugs

FINDING	STATE SURVEYED			
	Cross River	**Borno**	**Lagos**	**Kano**
Distribution and Supply				
Type of supply system	Push system of loose drugs: to LGAs and secondary health facilities; LGAs supply to primary health facilities	Simultaneous push and pull system of loose drugs: to LGAs which in turn supply to primary level facilities, secondary health facilities, schools, the army, the police, and mobile ambulance services	Push system of loose drugs: to LGAs and secondary health facilities; LGAs supply to primary health facilities	Push system of loose drugs: to LGAs and secondary health facilities; LGAs supply to primary health facilities
Capacity for efficient distribution	No	Yes	Inadequate transport facilities	Yes
Type and number of health facilities served	12 secondary health facilities, 18 primary health facilities	37 secondary health facilities, 7 LGA stores	1 teaching hospital, 12 general hospitals, 4 health centers, 57 local government clinics	16 general hospitals, 14 health centers, 7 LGA clinics, 8 LGA stores
Quality Control				
WHO Certification Scheme followed	Yes	Yes	Yes	No
Documents required for bidders	GMP certificate, certificate of analysis, manufacturer's license, NAFDAC	GMP certificate, manufacturer's license	GMP certificate, certificate of analysis, manufacturer's license, NAFDAC	NAFDAC
Inventory Control				
Written procedures available	No	Yes	Yes	Yes
Type(s) of inventory records	Store ledgers, bin cards	Tally cards, ledgers, store receipt vouchers, store issue vouchers	Ledgers, letters of award, invoices, way bills, daily issue, consolidated weekly issue, monthly returns, copies of requisition forms from LGA and secondary health facility medical stores	Store receipt vouchers, store ledgers, bin cards, store issue vouchers, invoices, receipts, waybills

FINDING	STATE SURVEYED			
	Cross River	**Borno**	**Lagos**	**Kano**
Method of product circulation in store	First in, first out (FIFO)	FIFO First expiry, first out (FEFO)	FIFO FEFO	FIFO
Timing of stock taking	Quarterly	Once a month	Once a month	Storage facilities
Procedure for allocation and distribution when shortages occur	Not determined	Dependent on hospital bed capacity	Malaria medicines provided to unit specializing in management of malaria	Redistribution from area with surplus to area with urgent need
Storage Facilities				
Availability of space for storage	Space, pallets, storage cabinets, and shelves adequate; forklifts, handling equipment need to be replaced	Space, shelves, and fire extinguishers adequate; pallets, storage cabinets, forklifts, handling equipment need to be replaced	Space adequate; pallets, storage cabinets, shelves, forklifts, handling equipment, fire extinguishers need to be replaced	Space, pallets, storage cabinets and shelves adequate; handling equipment needs to be repaired; forklifts and fire extinguisher needs to be replaced
Constraints to proper storage	Irregular power supply; no proper storage for vaccines	Broken central air conditioning	Irregular electricity; inadequate air conditioning; inadequate refrigerators	Power outages; maintenance problems with generator
Security	Adequate systems in place to prevent theft and leakage	Adequate systems in place to prevent theft and leakage	Adequate systems in place to prevent theft and leakage	Adequate systems in place to prevent theft and leakage
MIS and Information Flow				
Written information on store items available	Yes, monthly	Yes, monthly	Yes, monthly	Yes, monthly
Computerized system for:				
Tracking orders	No	No	No	No
Tracking delivery	No	No	No	No
Accounting/financial	No	No	No	Yes
Inventory control	No	No	No	Yes
Access to drug information resources	Yes: drug formulary, pharmaceutical journals	Yes: Web-based, official books, professional journals	Yes: Nigeria Drug Index, Emdex, British National Formulary, Pharmaceutical Codex, Martindale	No

FINDING	STATE SURVEYED			
	Cross River	**Borno**	**Lagos**	**Kano**
		Communications		
Communication devices in place	Telephone and Web site available	Telephone only; no fax, telex, or e-mail	Telephone, e-mail, and Web site available	Telephone only; no fax, telex, or e-mail
		Human Resources		
Adequate and appropriate staff	Yes	No	Yes	Yes
Major training needs	Training in the use of computers, effective store management courses	Inventory control, pharmacy management, computer applications	Store management course, advanced management course, computerized inventory implementation course, training in computer use	Information technology
Key problems for human resource development	None	Allocation of funds, lack of required personnel	Not all have been exposed to training in computer applications and store management	None

Rational Drug Use

Standard treatment guidelines are available in Nigeria to guide the use of medicines. At the primary level of health care, these are referred to as "Standing Orders." A National Drug Formulary published in 1994 is currently being updated. Development of STGs for all levels of the health care system is planned.

QUANTITATIVE FINDINGS, ANALYSIS, AND INTERPRETATION

Indicator 1. Percentage of median international price paid for a set of DMM antimalarials that were part of the last regular procurement

Description and Use of the Indicator

This indicator serves to help determine the potential savings to the MOH that could be achieved if procurement practices are first-rate and support changes in pharmaceutical systems. The lower the percentage, the greater the potential cost savings. The goal should be for the MOH to achieve at least or better than a 1:1 ratio when the MOH procurement price is compared to the international price. The desired change over time (if the indicator is monitored) is a decrease in the percentage of median international price (MIP) paid for a set of antimalarial drugs.

Methodology

The indicator was calculated by comparing the most recent MOH acquisition price for first- and second-line antimalarials purchased in 2004 to the MIP for procurement. The MIP is the median free on board (FOB) price for a set of international supplies, adjusted to reflect estimated cost, insurance, and freight (CIF)[9] prices. The MIP was obtained from the 2004 edition of the *International Drug Price Indicator Guide* published by MSH in collaboration with the World Health Organization.

Results

Information on CIF prices paid by the stores during the last regular procurement was obtained from tender documents and supplier invoices at the medical store level and from supplier invoices at the health facility level. Prices of antimalarial drugs were determined at four state medical stores, two LGA medical stores, and a sample of five general hospitals and two health centers. The MIPs for these drugs were also determined. In 2004, the state and LGA stores paid an average of 59 percent above the MIP for chloroquine tablets 150 mg, while the facilities paid an average of 210 percent above MIP. In 2004, the state and LGA stores paid an average of 280 percent above MIP for sulfadoxine-pyrimethamine 500 + 25 mg tablets, while the facilities paid an average of 670 percent above MIP.

[9] CIF, which stands for cost, insurance, and freight, is an International Commercial Term (INCOTERM) that includes the cost of the goods purchased plus the shipping and insurance costs of getting them to the designated port of entry of the destination country.

Table 4. First- and Second-Line Antimalarials Purchased above MIP in 2004

Antimalarial	Strength	Form	Adjusted MIP in USD	Percentage above MIP at Medical Stores	Percentage above MIP at Health Facilities
Chloroquine	150 mg	Tablet	0.0044	59	210
Sulfadoxine-pyrimethamine	500/25 mg	Tablet	0.04344	280	670

Discussion

At the state and LGA medical store level, it can be seen that the acquisition prices paid for first- and second-line antimalarials were very high. Factors that might have contributed to the MOH procurement prices being this high include the terms of tender, amounts ordered and potential economies of scale, and supplier prices for each medicine. In addition, the issue of contracting and lack of oversight in the process are contributory factors.

At the facility level, the MOH procurement prices for chloroquine and SP were even higher. This was probably because the drugs were being purchased from several sources at different prices, which might be a contributing factor to the inflated prices.

A major factor identified that leads to high procurement prices of medicines in Nigeria is that many different individuals and entities desire to do procurement. The procurement of medicines is seen as a very lucrative venture, and many institutions and facilities advocate for decentralization of procurement. While advocating for decentralization, minimal consideration is given to how affordable the medicines purchased will be to the end-user.

Indicator 2. Average percentage of a set of unexpired DMM antimalarial drugs available in (a) MOH storage and health facilities, (b) retail drug outlets, and (c) formal private health facilities

Description and Use of the Indicator

The indicator measures the availability of the DMM tracer list at the time of the study. A drug is defined as available if even one unit of unexpired product is in stock. Because expired drugs are inappropriate for use in almost all situations, they are not counted as stock available for use. Theoretically, all, or 100 percent, of the antimalarial drugs investigated should be unexpired and available all of the time at the different levels of health care in Nigeria. However, this indicator provides only a snapshot of the availability of drugs for malaria at the time of the study. The desired change over time of this indicator is an increase.

Methodology

To determine the percentage availability, existing inventory control systems—including manual ledgers and tally/bin/stock record cards—were examined.[10] Where none of the above-mentioned inventory control systems existed, monthly returns, vouchers, and drug requisition forms were examined. Antimalarials normally stocked at each level were first established. The rapid assessment then determined which of the normally stocked antimalarials were available.

Results

An average of 27 percent of tracer drugs was found in state medical stores (Table 4).

Table 5. Availability of Antimalarial Drugs on the Tracer List at the Health Facilities

Facility Type	Number of Facilities	Average % of Tracer List Available
Health center	11	13.3
General/specialist/tertiary hospital	9	26.1
LGA medical store	2	14.6
State medical store	4	27.0

Examination of similar inventory control systems revealed that an average of 14.6 percent of tracer drugs was found at the local government medical store level and an average of 41.6 percent of tracer drugs was found at the general hospital store level. An average of 26.1 percent of tracer drugs was found in the general, specialist, tertiary, and secondary public facilities and an average of 23.6 percent found in the private hospitals, nursing homes, and maternity clinics visited. At the government health center level—including primary health centers and polyclinics—the percentage of tracer drugs found was as low as 13.3 percent.

[10] No operational computerized inventory control systems existed at any of the sites visited during the assessment.

Table 6. Availability of Antimalarials in the Medical Stores Compared to the Drug Retail Outlets

Tracer List	% Available in Stores	% Available in Private Pharmacies/Drug Outlets
Amodiaquine 200 mg tablet	0	20
Artemether injection 80 mg/mL in 1 mL ampoule	14	20
Artemether-lumefantrine 20 mg/120 mg tablet	0	15
Artesunate 50 mg tablet	28	27.5
Artesunate 200 mg rectocap	0	7.5
Chloroquine 50 mg tablet	0	12
Chloroquine 75 mg tablet	0	7.5
Chloroquine 150 mg caplet	14	17.5
Chloroquine 150 mg tablet	57	82.5
Chloroquine 300 mg capsule	14	25
Chloroquine 300 mg tablet	0	15
Chloroquine injection 40 mg/mL in 5 mL ampoule	85	—
Chloroquine syrup 50 mg/5 mL	100	82.5
Dihydroartemisinin 80 mg tablet	28	30
Halofantrine 250 mg tablet	14	37.5
Mefloquine 250 mg tablet	14	7.5
Mefloquine/sulfadoxine-pyrimethamine 250 mg/500 mg/ 25 mg tablet	0	20
Proguanil hydrochloride 100 mg tablet	28	22.5
Pyrimethamine 25 mg tablet	43	52.5
Quinine 300 mg tablet	0	25
Quinine injection 300 mg/mL in 2 mL ampoule	43	—
Sulfadoxine-pyrimethamine 500 mg/25 mg in 2.5 mL ampoule	0	30
Sulfadoxine-pyrimethamine 500 mg/25 mg in 5 mL syrup	28	5
Sulfadoxine-pyrimethamine 500 mg/25 mg tablet	71	95

An average of 31.4 percent of tracer drugs was found in the private pharmacies/drug retail outlets visited. In all, a total of 40 pharmacies/drug retail outlets were surveyed in the four states. The findings in Table 5 show that the availability of antimalarial drugs is higher in the private pharmacies/drug retail outlets than in the public sector medical stores.

Discussion

The successful implementation of a new antimalarial drug treatment policy is dependent on the recommended drugs being available in either the public or private sectors. If they are not, patients may not receive proper treatment. This indicator is a measure of the efficiency of the procurement and distribution system.

Overall, almost three-quarters of the tracer drugs were absent in more than half of the visited government facilities. Some drugs, despite being on the EDL, were never available in any facility because they had not been part of procurement by the states or LGAs and had never entered the distribution system from another source.

A pattern of decreasing availability of drugs with increasing distance from the center of the distribution system was noted, with availability being higher at the medical store level and lower at the health facility level. This analysis was done using the 24 tracer drugs as the denominator. Ideally, the availability of drugs should be lowest at the center of storage and highest at peripheral levels where patients are treated. Availability at the periphery—in this case, the health center level—depends on the distribution system from the state and LGA medical store levels.

To determine why availability of antimalarials in Nigeria is low requires further analysis. Some explanations might be problems in the areas of budgeting, theft, wastage, quantification, delivery problems, and/or inventory management. Once the specific causes have been identified, potential interventions can be developed.

Indicator 3. Average percentage of time out of stock for a set of DMM antimalarial drugs in MOH storage and health facilities

Description and Use of the Indicator

A corresponding indicator of availability is a measure of stock-outs during a period of time. Used in tandem with Indicator 2, the stock-out indicator allows for a stronger analysis of the stock situation over time. The percentage of time out of stock for a set of DMM antimalarial drugs gives a measure of the procurement and distribution system's performance in maintaining a constant supply of drugs. The successful treatment of malaria is dependent on the drugs being available. The ideal target for this indicator is 0 percent, or no stock-outs, and the desired change is a decrease from whatever is measured.

Methodology

The information for this indicator was gathered from tally/bin/stock cards as well as manual ledgers in some instances. Where none of the above was available, store receipt vouchers, drug revolving fund requisition forms, SIVs, receipts of purchase, and monthly returns were used.

Time out of stock was defined as the number of days that a product was not present in a warehouse or health facility over a recent 12-month period. The time period set for this assessment was from March 2003 to February 2004. To be considered a stock-out, none of an unexpired drug should be in stock.

Results

Analysis revealed that overall, antimalarial drugs were out of stock 20.9 percent of the time over the indicated period. This percentage was determined by first calculating the total number of

days out of stock for all **stocked** drugs at each facility. Then the following calculation was applied to determine average percent time out of stock:

$$\frac{\text{Total number of days out of stock for all stocked drugs} \times 100}{365} \times \text{Total number of products stocked}$$

The average time out of stock for all facilities was then calculated.

Table 7. Average % of Days Out of Stock of Antimalarial Drugs by Facility Type

Facility Type	Number of Facilities	Average Percent of Days Out of Stock
State/LGA medical store	3	14
General hospital	11	31
Health center	7	15

Discussion

The overall average percent of days out of stock appears not to be too high, which indicates relatively ready access to drugs for the Nigerian population in the event of a policy change. It can be seen in Table 6 that the shortest time out of stock is seen at the central level (14 percent) and the health center level (15 percent) and the longest at the general hospital level (31 percent). This needs further investigation to determine why the general hospitals assessed have a higher percentage. Further investigation might include a check for seasonal variations by extending the 12-month period to an additional 24-month period, as well as examination of changes in stock levels that correlate with procurement activities and with stock levels at the state medical stores and LGA stores to determine if problems exist in the distribution pipeline.

Indicator 4. Average percentage of stock records that correspond with physical counts for a set of DMM antimalarial drugs in MOH storage and health facilities

Description and Use of the Indicator

The average percentage of stock records that correspond with physical counts is a measure of the quality of the stock record-keeping system. This indicator helps reveal inventory management problems and may point to the need for further assessments of problems such as wastage, pilferage, and poor record-keeping, all of which contribute to poor service delivery and financial losses. The indicator calculates the average percentage of in-stock DMM antimalarial drug inventory records that corresponds exactly with a physical stock count for a set of DMM antimalarial drugs.

Methodology

The most accurate stock records of current stock level for each of the DMM antimalarial drugs were reviewed by data collectors. Where stock records and physical counts did not correspond, recent issues or receipts that had not been posted were reviewed and adjusted stock records were calculated.

Results

After adjusting for issue and receipt tickets not yet recorded in state and LGA medical stores, the percentage of records for the tracer list of 24 antimalarials that correspond with physical counts was 47 percent. The average percentage of health facility records that correspond with physical counts was 33 percent, with the range among facilities from 15 percent to 50 percent.

Discussion

The low percentage of correspondence may suggest a need to review the record-keeping system. Training may be needed in math skills, stock record-keeping, and/or inventory procedures.

Indicator 5. Percentage of MOH health facilities with an official manual of treatment guidelines for malaria

Description and Use of the Indicator

Theoretically, all, or 100 percent, of facilities should have an official copy of treatment guidelines. This indicator is used to measure the level of access of information to promote effective care and management of malaria based on the treatment guidelines put out by the FMOH in Nigeria. Although the presence of guidelines does not mean that the staff uses them, and although they do not ensure rational prescribing, treatment guidelines do provide a reference source that supports more appropriate prescribing. Private facilities were not assessed for this indicator.

Methodology

The rapid assessment determined the presence of STGs at facilities visited. The STGs as put forth by the FMOH in Nigeria is the main document intended as a clinical reference for health care providers who diagnose and treat malaria patients. Staff of primary-level health facilities use official Standing Orders.

Results

Of the 21 facilities surveyed for the presence of STGs, 11 were health centers and 10 general hospitals. Only one of the 11 health centers (9 percent) had a copy of the latest version of the standard treatment guidelines and could produce it. The same was the case in the 10 general

hospitals. Three health centers (27 percent) had a copy of the Essential Drugs List, and two general hospitals (18 percent) had a copy of the EDL.

Discussion

The provision of STGs and Standing Orders at health facilities in Nigeria is dependent on the availability of resources within the FMOH for production of adequate copies. In addition, the distribution of the guidelines should be accompanied by training in the use of the guidelines.

Indicator 6. Percentage of encounters diagnosed as uncomplicated malaria that are prescribed antimalarials consistent with treatment guidelines

Indicator 7. Percentage of encounters with patients diagnosed with uncomplicated malaria that are prescribed adequate quantities of appropriate antimalarials sufficient to complete a full course of treatment

Description and Use of the Indicators

These two indicators (6 and 7) measure the degree of adherence to national malaria treatment guidelines. High percentages identify a positive behavior that should be reinforced or encouraged. Low percentages identify the need for improvement. Low percentages for Indicator 7 could indicate that patients do not complete a course of treatment. This behavior could have potentially serious consequences for the patient as well as contributing toward drug resistance.

Methodology

Indicators 6 and 7 were calculated from retrospective prescription data.

Results

Of a total of 585 patient records studied, 76 percent were diagnosed as uncomplicated malaria (between March 2003 and March 2004) and received chloroquine treatment, 8.8 percent received sulfadoxine-pyrimethamine, and the remaining 15.2 percent received generic antimalarials including quinine, artemether, and halofantrine, as well as brand-name drugs such as Metakelfin (quinine and sulfalene-pyrimethamine), Plasmotrin (artesunate), Cotexin (dihydroartemisinin), Coartem (artemether-lumefantrine), Alaxin (dihydroartemisinin), and Paludrine (proguanil).

Simulated purchases conducted at 37 drug retail outlets showed that chloroquine was prescribed in 80 percent of the encounters presenting with complaints compatible with uncomplicated malaria.

Discussion

Because the development of resistance to antimalarials is a central problem in treating malaria, a key strategy to slow the spread of resistance is to ensure that patients complete the full course of therapy. Analysis showed that patients diagnosed with uncomplicated malaria were prescribed adequate quantities of appropriate antimalarials[11] for their respective age groups. It can be argued that a full course of treatment for both chloroquine and SP are fairly well known to both health personnel and patients/caregivers, and due to the short duration of treatment with these drugs and the relatively low costs associated with purchasing complete doses, it is not surprising that most encounters surveyed received a complete course of treatment. When artemisinin-based combination therapies are procured and distributed under the new Nigerian antimalarial drug treatment policy, the MOH will have to monitor this indicator to ensure compliance with the policy and prevent resistance development.

The findings of 80 percent of encounters being prescribed an appropriate antimalarial in the drug retail outlets was also encouraging as it means that private pharmacies/drug retail outlets are not only interested in selling antimalarials that would give them a high profit margin but also in providing treatments that are nationally recommended.

Indicator 8. Percentage of prescribed antimalarial drugs actually dispensed by public health facilities

Description and Use of the Indicator

This indicator measures the ability of a sample of health facilities to dispense the prescribed antimalarial drugs to malaria patients/caregivers of malaria patients. Theoretically, all, or 100 percent, of drugs prescribed should be dispensed. Low percentages identify problems of availability or poor dispensing practices.

Methodology

A review of patient records was conducted.

Results

Analysis showed that over 80 percent of patients prescribed chloroquine and SP had the quantity prescribed dispensed at the same facility. Drugs such as Metakelfin, halofantrine tablets and syrup, and Cotexin and Paludrine tablets, although prescribed, were not dispensed at the facility.

[11] Appropriate antimalarials include those antimalarials listed in Nigeria's national treatment guidelines.

Table 8. Percentage of Prescribed Antimalarials That Were Actually Dispensed at the Health Facility

Facility Type	Number of Antimalarial Drugs Prescribed	Number (%) Dispensed as Prescribed
General hospital	300	262 (87%)
Health centers	285	228 (80%)
Overall	585	490 (84%)

Discussion

As can be seen in Table 7, the majority (84 percent overall) of patients received their medicines as prescribed. This indicator value is higher for general hospitals (87 percent) than for health centers (80 percent). There are several possible reasons for this difference: availability of certain medicines at the more peripheral facilities might be poor; patients may prefer to buy their medicines from a private pharmacy; patients might not have had enough money with them and would have had to go and consult the head of household with regard to the purchase of prescribed drugs.

Indicator 9. Average cost of drugs prescribed as a percentage of costs if STG norms for treatment were followed

Description and Use of the Indicator

One of the basic tenets of rational pharmaceutical management is that if standardized treatment guidelines are followed, the cost of care is likely to be less than the cost of care if guidelines are not followed. On the basis of this assumption, this indicator measures the average cost of antimalarial drugs actually prescribed for malaria treatment and then compares that with what drug treatment would cost if STGs were not followed.

This indicator is used to quantify the financial burden of not complying with STGs to encourage the undertaking of interventions to improve drug use. The desired change over time for this indicator is a decrease in percentage. The indicator measures the average cost of drugs prescribed currently in Nigeria for different age groups in the public and private sectors and compares the average to what drug treatment would cost if STGs were followed for those age groups. The comparison is depicted mathematically as a percentage for each age group in each sector.

Methodology

To calculate the indicator value, all drugs prescribed for the patient encounters in the health facilities as well as those prescribed for the sample of simulated purchases were reviewed.

Results

For the surveyed health facilities during the rapid assessment, the average cost of drugs prescribed for the treatment of malaria in adults was 0.68 U.S. dollars (USD). This cost is only slightly higher than the cost of antimalarial treatment recommended by the STGs. For children between one and five treated at the same group of health facilities, the average cost of antimalarial medicines was USD 0.30. For the simulated purchases, the average cost of malaria treatment was USD 5.40.

Indicator 10. Percentage of caregivers who could correctly describe how to give the prescribed medication

Description and Use of the Indicator

This indicator is useful to measure the potential for non-adherence and possible treatment failure resulting from a lack of knowledge of patients and caregivers on how to administer medication correctly. Together with Indicator 11, this indicator can help pinpoint communication problems between the health worker and the patients/caregivers. A low percentage indicates that health workers are not providing enough information to patients/caregivers about the medication, which could be a reason for non-adherence to treatment. Ideally, every patient and caregiver should know the name of the drug prescribed, what the drug is prescribed for, the dose, the frequency, how to administer the drug, and the number of days the drug should be given. The desired change over time is an increase in the indicator.

Methodology

Calculation of this indicator was done using observation data from consultations as well as from exit interviews of patients/caregivers.

Results

Of the 12 different antimalarials prescribed in public facilities, only 58 percent could be correctly administered according to the knowledge of the patient/caregiver on leaving the facility.

Table 9. Percentage of Patients/Caregivers That Could Correctly Describe the Administration of Their Prescribed Antimalarials

Facility Type	Number of Antimalarial Prescriptions Surveyed	Administration Correctly Described by Patient/Caregiver (%)
General/specialist/secondary/ tertiary hospital	135	66 (48.8%)
Private hospital	5	4 (80%)
Health center/PHC clinic	65	44 (67.7%)

Discussion

The indicator is a judgment of whether the patient/caregiver understood how to administer the drugs correctly at home and, therefore, whether there is a chance the drugs will actually be administered correctly. The relatively low percentage of 58 percent indicates that health workers or drug dispensers are not providing enough information to patients about the medication, which can lead to non-adherence and treatment failure.

It can be seen in Table 8 that private hospitals had the highest percentage of patient/caregivers who could correctly describe antimalarial administration as instructed by the health worker. This is probably due to the fact that private hospitals see fewer patients who pay more and therefore more time is taken to communicate with patients receiving malaria treatment and/or their caregivers. Secondary and tertiary facilities of the health care system had the lowest percentage of patients/caregivers who would be likely to correctly administer the antimalarial drugs prescribed. Again, this could be due to the presence of overwhelmingly large numbers of patients visiting the facility. This indicator, although used, is deemed to be somewhat subjective because the responses elicited from the patients/caregivers upon leaving the facility do not indicate how the drugs will actually be administered in the home.

In approximately 10 percent of exit interviews, patients/caregivers did not know the name of the antimalarial drug but knew the quantity to take and duration of treatment in days. The identification of specific communication problems and investigation of the usefulness of alternative communication strategies can be used as a basis for improvement of rational use of medicines.

Indicator 11. Percentage of health workers who provided [some] information to patient/caregivers on how to give the recommended drug(s)

Description and Use of the Indicator

This indicator measures whether health workers are able to communicate to patients how to take their medication. This component is important in gaining an understanding of patient use of medication and patient education. The definition for “some information” includes the dose and the frequency of medication use, how to prepare the drug, whether to take it with food, or any potential side effects of symptoms associated with the drug. During the assessment, if the health worker explained at least one of the aspects mentioned above to the patient/caregiver, then for this indicator, it was considered that the health worker provided some information regarding the prescribed drug.

Methodology

Calculations for the indicator were done only on the basis of observational data from consultations by health workers.

Results

As shown in Table 9, health workers had a relatively high level (99.6 percent across all facilities) of communication to patients/caregivers of information about dosing of drugs.

Table 10. % of Health Workers Who Provided Information to Patients/Caregivers on How to Give the Recommended Antimalarial Drugs

Facility Type	Number of Health Workers Surveyed	Number (%) Providing Information on How to Take Medicine
General/specialist/tertiary hospital	142	141 (99%)
Private hospital	5	5 (100%)
Health center/PHC clinic	71	71(100%)
Overall	218	217 (99.6%)

In the 40 simulated purchases at the drug retail outlets, all the health workers provided some information to the patient/caregiver on how to give the recommended drug(s).

Discussion

The communication of information about the dosage of drugs by health workers to patients/caregivers was found to be high. This percentage is slightly lower in general hospitals than in health centers, which suggests that practitioners are following the guidelines. Malaria training among health workers in Nigeria obviously emphasizes communication of correct content between the health worker and the patient/caregiver.

Indicator 12. Percentage of encounters with pregnant women living in endemic areas who are prescribed an appropriate antimalarial for intermittent preventive treatment at antenatal clinics

Description and Use of the Indicator

This indicator is designed to measure the extent to which pregnant women attending antenatal clinics are offered SP for IPT in line with the country's malaria treatment guidelines. High percentages identify a positive behavior that should be reinforced or encouraged. Low percentages identify the need for improvement.

Results

Analysis showed that 5 (9.3 percent) out of 54 of pregnant women who received prophylaxis at the general hospital received sulfadoxine-pyrimethamine (3 tablets); 23 (42.6 percent) received pyrimethamine 25 mg tablets; one (1.9 percent) received a course of artesunate; and the remaining 25 (46.2 percent) received chloroquine in one form or another, such as injection or

tablets (doses included 50 mg stat, 150 mg stat, 300 mg stat, 600 mg stat, and the full course of 10 tablets).

At the health center level, 6 (35.3 percent) of 17 pregnant women who received prophylaxis were given pyrimethamine 25 mg tablets and the remaining 11 (64.7 percent) received some form of chloroquine in doses similar to those given at the general hospitals.

Table 11. Percentage of Pregnant Women Who Received IPT with SP

Facility Type	Number of Pregnant Women Surveyed	Number of Pregnant Women Who Received Prophylaxis	Number (%) of Pregnant Women Who Received Prophylaxis Who Were Given an Appropriate Antimalarial
General/specialist/secondary/ tertiary hospital	100	54	5 (9.3%)
Health center	48	17	6 (35.3%)

Discussion

Overall in the health facilities surveyed during the assessment, an appropriate antimalarial was prescribed for prophylaxis in only 7.4 percent of all antenatal encounters. This percentage is very low; possible reasons include a lack of adequate education among both health workers and pregnant women of the importance of IPT with SP.

LIMITATIONS OF THE DATA

Standardized indicators to assess pharmaceutical sectors have been widely used for many years by Management Sciences for Health/Rational Pharmaceutical Management Plus and other organizations such as the World Health Organization and Pan American Health Organization. Such indicator-based studies are cost-effective tools that measure complex systems in a relatively short time and give investigators a snapshot of overall trends in the sector (Bates, 1995).

The design of the study had the following limitations:

- It was a rapid assessment and was not intended for in-depth determination of all problems identified but rather flagged the problems for the FMOH to follow up on.

- The methodology used was not intended to conduct a complete assessment of the entire pharmaceutical system.

- The rapid assessment is based on the assumption that the drugs on the country's standard treatment guidelines are appropriate. The study design does not provide an assessment of clinical appropriateness of the guidelines in existence.

- This assessment neither measured health-seeking behavior nor patient compliance. Therefore, an understanding of the factors that influence a patient's decision to seek treatment as well as the decision to comply with the recommended treatment were not determined and would require further investigation.

- The appropriate diagnosis of malaria was not assessed.

- Only 4 states out of 36 were sampled; therefore, these results cannot be generalized countrywide. The assessment was conducted to quickly determine what barriers exist to the smooth implementation of an ACT policy.

CONCLUSION

This rapid assessment highlights some challenges in Nigeria's pharmaceutical management system and shows need for improvement in all areas of the pharmaceutical management cycle.

Selection of medicines for use in malaria control in Nigeria is done at the federal level of government and incorporated into the national Essentials Drug List, which the assessment found to be regularly updated to meet the needs of most of the country. Manufacturers, distributors, and facilities, both public and private, largely adhere to the medicines listed on the EDL. Adherence to the EDL is facilitated by the presence of efficient regulatory agencies in-country.

Procurement of antimalarial medicines is decentralized to the state, LGA, and facility levels. States have seemingly adopted procurement and distribution systems that serve to suit their particular requirements. However, the highly decentralized nature of procurement, even to the smallest facility level, is prejudiced by the individual desire for profits, with not much consideration given to the cost of medicines to the end-user. The costs of antimalarial medicines in most states is absorbed by the government through drug revolving fund schemes. Patients are charged only registration fees.

Antimalarials have limited availability, with better availability in the state medical stores and lower availability at the health facility level. The health facilities surveyed had stock-outs of antimalarial medicines.

Reference sources on appropriate diagnosing and prescribing practices, such as the STGs, were found to be absent in most facilities surveyed. In spite of this, health workers in facilities surveyed had adequate prescribing practices.

Private sector drug retail outlets prescribe and dispense nationally recommended treatments for malaria. The average costs of malaria treatment are higher in the private drug retail outlets. Patients receiving care from private facilities and retail outlets are more likely to be able to correctly describe antimalarial administration.

An efficient pharmaceutical management system should result in the availability of appropriate antimalarials in adequate quantities all the time. This is not the case in Nigeria, and improvement is needed in the system to accommodate the implementation of an ACT policy. In summary, the key challenges observed by the rapid assessment might be said to include the following:

- Unconsolidated procurement of medicines
- Inadequate inventory and stock management
- Poor record-keeping in facilities
- Frequent stock-out of antimalarial drugs

RECOMMENDATIONS AND NEXT STEPS

The findings of the rapid assessment presented in this report indicate specific problems in the availability and use of antimalarial medicines in Nigeria. The indicators presented in the report should be viewed as the first step in a process of investigation of the problems discussed in the report. The findings are meant to help the RBM unit of the FMOH identify the challenges that will come with the implementation of the new ACT policy. These challenges should be discussed by key RBM stakeholders and stakeholders in the pharmaceutical sector with the aim of improving the system. This report can serve as an advocacy tool to prompt policy makers to write policies that improve the availability of affordable medicines.

The rapid nature of this assessment did not allow for in-depth determination of the challenges identified. It is therefore recommended that further investigation using more qualitative methods be done to determine reasons for the challenges identified (Bates, 1995).

Pharmaceutical management–specific recommendations to ensure the smooth implementation of the new ACT policy are as follows:

Federal Ministry of Health

- Evaluate further the pharmaceutical management system to determine best practices with respect to selection, procurement, distribution, and rational use of medicines, including antimalarials

- Guide public pharmaceutical management practice by stating and implementing policies that would lead to the effective selection, procurement, distribution, and rational use of medicines, including antimalarials

- Identify funding sources for procurement of artemether-lumefantrine to ensure that adequate quantities are made available

- Assess suppliers, both local and international, to ensure increased availability of artemether-lumefantrine

- Attain competitive price for artemether-lumefantrine using the *International Drug Price Indicator Guide* published by MSH in collaboration with the World Health Organization as a guide

- Enforce drug quality through continuous monitoring by National Agency for Food and Drugs Administration and Control (NAFDAC), as the cost of artemether-lumefantrine will tend to encourage counterfeiting

- Make available standard, simple store management tools such as reporting forms, stock cards, and ledgers within federal, state, and LGA stores and at all levels of the primary health care (PHC) system

Roll Back Malaria Unit

- Advocate for bulk procurement of artemether-lumefantrine to ensure low purchase costs resulting in financial accessibility to the population
- Integrate the distribution of artemether-lumefantrine under the new policy into existing systems to ensure sustainability
- Ensure adequate production and wide dissemination of new treatment policy and standard treatment guidelines amongst relevant stakeholders and to health facilities in both the public and private sectors of Nigeria. The availability of these documents will give health workers assess to good reference material, enabling them to be conversant with the ACT regimens.
- Reinforce positive prescribing and dispensing behaviors by training and supporting providers, dispensers, and shopkeepers in both the public and private sectors
- Initiate training of relevant personnel in the medical stores and health facility stores at all levels of the PHC system to enable efficient pharmaceutical management of artemether-lumefantrine within the public sector. Training would include record-keeping, inventory, and store management.
- Undertake effective demand creation for the introduction of artemether-lumefantrine
- Continue to collaborate with managers of other sectors to ensure a coordinated approach to the delivery of effective malaria treatment and preventive measures by formal and informal practitioners

Pharmaceutical Sector Stakeholders

- Advocate for and provide technical assistance to the FMOH for the establishment of efficient pharmaceutical management systems
- Make available to the FMOH, federal medical stores, and LGA medical stores hard copies of the *International Drug Price Indicator Guide* published by MSH in collaboration with the World Health Organization for use as a reference
- Provide support for the training of relevant personnel in the medical stores and health facility stores at all levels of the PHC system to enable efficient pharmaceutical management within the public sector. Training would include record-keeping, inventory, and store management.
- Work with the RBM unit to investigate franchising and accreditation of drug retail outlets

Donors

- Treat pharmaceutical management as a high priority for public health in Nigeria and therefore provide support to the FMOH for activities aimed at strengthening the system

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ANNEX 1. DATA COLLECTION TOOLS

DAS-2B-D: Inventory Data Form: Health Facility and Medical Stores

Facility Code:	**Data Collector Code:**	
Facility Type:	**Location:**	**Date:**

Existing inventory control systems:
Computerized
Manual Ledger
Tally / Bin / Stock Record Cards
Other (specify)

Data collected from:
Computerized
Manual Ledger
Tally / Bin / Stock Record Cards
Other (specify)

Note:

- **Data collectors should not fill out the shaded rows or columns.**
- *All* blanks should be filled in on this data form (other than those in the shaded rows or columns).
- Enter N/A if data for a particular item are not available from the records or from the health care workers.

DAS-2B-D: Inventory Data Form [page 2 of 3]

Product	Counting Unit	Record Count	Unposted Receipts	Unposted Issues	Adjusted Total	Physical Count	Expired Stock	Non-expired Stock Available
Col. 1	**Col. 2**	**Col. 3**	**Col. 4**	**Col. 5**	**Col. 6**	**Col. 7**	**Col. 8**	**Col. 9**
Amodiaquine 200 mg tablet	Tablet							
Chloroquine 50 mg tablet	Tablet							
Chloroquine 75 mg tablet	Tablet							
Chloroquine 150 mg capsule	Capsule							
Chloroquine 150 mg tablet	Tablet							
Chloroquine 300 mg capsule	Capsule							
Chloroquine 300 mg tablet	Tablet							
Chloroquine injection 40 mg/mL in 5 mL ampoule	Ampoule							
Chloroquine syrup 50 mg/5 mL	Milliliter							
Proguanil hydrochloride 100 mg tablet	Tablet							
Pyrimethamine 25 mg tablet	Tablet							
Quinine 300 mg tablet	tablet							
Quinine injection 300 mg/mL in 2 mL ampoule	Ampoule							
Sulfadoxine-pyrimethamine (SP) 500 mg/25 mg in 2.5 mL ampoule	Ampoule							
Sulfadoxine-pyrimethamine (SP) 500 mg/25 mg in 5 mL syrup	Milliliter							
Sulfadoxine-pyrimethamine (SP) 500 mg/25 mg tablet	Tablet							
Row 1: Total number of products for which Col. 6 equals Col. 7								
Row 2: % of records corresponding with physical counts: number in Row 1 x 100/ total number of products stocked in Col. 1								
Row 3: % of antimalarials available								

DAS-2B-D: Inventory Data Form [page 3 of 3]

Product	Counting Unit	Record Count	Unposted Receipts	Unposted Issues	Adjusted Total	Physical Count	Expired Stock	Non-expired Stock Available
Col. 1	**Col. 2**	**Col. 3**	**Col. 4**	**Col. 5**	**Col. 6**	**Col. 7**	**Col. 8**	**Col. 9**
Artemether injection 80 mg/mL in 1 mL ampoule	Ampoule							
Artemether-lumefantrine 20 mg/120 mg tablet	Tablet							
Artesunate 50 mg tablet	Tablet							
Artesunate 200 mg rectocap	Rectocap							
Dihydroartemisinin 80 mg tablet	Tablet							
Halofantrine 250 mg tablet	Tablet							
Mefloquine 250 mg tablet	Tablet							
Mefloquine/sulfadoxine-pyrimethamine 250 mg/500 mg/25 mg tablet	Tablet							
Proguanil hydrochloride 100 mg tablet	Tablet							
Row 1: Total number of products where Col. 6 equals Col. 7								
Row 2: % of records corresponding with physical counts: number in Row 1 x 100/ total number of products stocked in Col. 1:								
Row 3: % of antimalarials available								

DAS-2E: Inventory Data Form: Private Pharmacy/Drug Retail Outlet

Drug Outlet Code:	**Data Collector Code:**	
Drug Outlet Type:	**Location:**	**Date:**

Product	**Product Available (Yes/No)**
Col. 1	**Col. 2**
Amodiaquine 200 mg tablet	
Artemether injection 80 mg/mL in 1 mL ampoule	
Artemether-lumefantrine 20 mg/120 mg tablet	
Artesunate 200 mg rectocap	
Artesunate 50 mg tablet	
Chloroquine 50 mg tablet	
Chloroquine 75 mg tablet	
Chloroquine 150 mg capsule	
Chloroquine 150 mg tablet	
Chloroquine 300 mg capsule	
Chloroquine 300 mg tablet	
Chloroquine syrup 50 mg/5 mL	
Dihydroartemisinin 80 mg tablet	
Halofantrine 250 mg tablet	
Mefloquine 250 mg tablet	
Mefloquine/sulfadoxine-pyrimethamine 250 mg/500 mg/25 mg tablet	
Proguanil hydrochloride 100 mg tablet	
Pyrimethamine 25 mg tablet	
Quinine 300 mg tablet	
Sulfadoxine-pyrimethamine 500 mg/25 mg in 5 mL syrup	
Sulfadoxine-pyrimethamine 500 mg/25 mg tablet	
Row 1: % of antimalarials available	

DAS-3B-D: Stock-Out Data Form: Health Facility and Medical Stores

Facility Code:	**Data Collector Code:**		
Facility Type:	**Location:**	**Date:**	**Record Type:**

Product (Col. 1)	Number of Days Out of Stock per Month												Total Days Out of Stock
	Feb 2004	Jan 2004	Dec 2003	Nov 2003	Oct 2003	Sep 2003	Aug 2003	Jul 2003	Jun 2003	May 2003	Apr 2003	Mar 2003	
Amodiaquine 200 mg tablet													
Chloroquine 50 mg tablet													
Chloroquine 75 mg tablet													
Chloroquine 150 mg capsule													
Chloroquine 150 mg tablet													
Chloroquine 300 mg capsule													
Chloroquine 300 mg tablet													
Chloroquine injection 40 mg/mL in 5 mL ampoule													
Chloroquine syrup 50 mg/5 mL													
Proguanil hydrochloride 100 mg tablet													
Pyrimethamine 25 mg tablet													
Quinine 300 mg tablet													
Quinine injection 300 mg/mL in 2 mL ampoule													
Sulfadoxine-pyrimethamine 500 mg/ 25 mg tablet													
Sulfadoxine-pyrimethamine 500 mg/ 25 mg in 2.5 mL ampoule													
Sulfadoxine-pyrimethamine 500 mg/ 25 mg in 5 mL syrup													
Row 1: Total number of days out of stock for all stocked drugs:													
Row 2: Total number of products stocked in Col. 1													
Row 3: Average % time out of stock = (number in Row 1 x 100)/(365 x number in Row 2)													

DUS-1A: Medical Records and Facility Resources Review Form

Facility Code:	**Data Collector Code:**	**Facility Type:**	
Location:	**Date:**	**Currency Used:**	**One U.S. Dollar =**

1. Does the facility have a copy of the national standard treatment guidelines for malaria?

   Yes No

   If yes, from what year?_____

2. Does the facility have a copy of the National Standing Order for treatment?

   Yes No

   If yes, from what year?_____

3. Does the facility have a copy of the National Essential Drugs List?

   Yes No

   If yes, from what year?_____

Data collected from: Patient registry
Patient records
Prenatal records
Health facility staff

DUS-1A: Medical Records and Facility Resources Review Form: Uncomplicated Malaria [page 2 of 2]

Facility Code:	Data Collector Code:

Encounter Number	Age (Years)	Sex (M/F)	Pregnant (Yes/No)	Date	Prescriber Type	Product Name, Strength, and Dosage Form	Quantity Prescribed	Quantity Dispensed	Facility Price	Retail Outlets: Number of Units	Retail Price	Full Course Prescribed (Yes/No)	Full Course Dispensed (Yes/No)
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7	Col. 8	Col. 9	Col. 10	Col. 11a	Col. 11b	Col. 12	Col. 13
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													

DUS-1B: Medical Records and Facility Resources Review Form: Pregnant Women

Facility Code:	**Data Collector Code:**	**Facility Type:**	
Location:	**Date:**	**Currency Used:**	**One U.S. Dollar =**

Encounter Number	Age (Years)	Prescribed Prophylaxis (Yes/No)	Date	Prescriber Type	Product Name, Strength, and Dosage Form	Quantity Prescribed	Quantity Dispensed	Number of Units	Facility Price	Full Course Prescribed (Yes/No)	Full Course Dispensed (Yes/No)
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7	Col. 8	Col. 9	Col. 10	Col. 11	Col. 12
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											

DUS-2: Observation of Health Worker Data Form

Facility Code:	**Data Collector Code:**	**Facility Type:**	
Location:	**Date:**	**Encounter Number:**	
Patient Sex (M/F):	**Pregnant (Y/N):**	**Age:**	**Diagnosis:**

A. Write down exactly any questions that the prescriber/health worker asks the patient/caregiver about the illness or symptoms of illness.

B. Write down exactly what the prescriber/health worker says about what the patient/caregiver should do if the illness does not get better.

DUS-2: Observation of Health Worker Data Form [page 2 of 2]

For each medicine that the health worker/prescriber gives or prescribes, write down the following information.

Product Name, Strength, and Dosage Form	Dosage Quantity	Frequency	Duration of Treatment (Days)	Mode of Administration	Full Course Prescribed (Yes, No, N/A)
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6

1. Did the health worker explain to the patient/caregiver how to take/give the medication?	YES NO
2. Was treatment consistent with STGs?	YES NO
3. Did the health worker ask one or more clinical questions to determine the severity of malaria? (*optional)*	YES NO
4. Did the health worker tell the patient/caregiver about any signs of progressive illness and recommend a referral visit if the signs appear? *(optional)*	YES NO

DUS-3: Patient/Caregiver Exit Interview Form

Facility Code:		**Data Collector Code:**	
Facility Type:	**Location:**	**Date:**	**Encounter Number:**
Interview Number:	**Age (years/months):**	**Sex (M/F):**	**Pregnant (Y/N):**

1. Ask the patient/caregiver: "What was the chief complaint or the reason for the consultation (i.e., the health problem)?"

   Fever
   Headache
   Joint pain
   Malaria
   Other/specify _____

2. Ask the patient/caregiver: "What medicines were prescribed and how are you going to take/give them to the patient?"

Name of Product	Dosage Quantity	Frequency	Duration of Treatment (Days)	Administration	Did the Patient/Caregiver Receive the Medicine? (Yes/No)	Quantity Dispensed
Col. 1	**Col. 2**	**Col. 3**	**Col. 4**	**Col. 5**	**Col. 6**	**Col. 7**
Row 1: Total number of medicines prescribed						
Row 2: Can patient/caregiver correctly describe how to give prescribed medications?						**Yes No**
Row 3: Total number of medicines dispensed						
Row 4: Did the prescription cover a full course of treatment?						**Yes No**
Row 5: Did the quantity dispensed cover a full course of treatment?						**Yes No**

DUS-4: Simulated Purchase Form for Uncomplicated Malaria in Private Pharmacies

Facility Code:		**Data Collector Code:**	
Location:	**Date:**	**Currency Used:**	**One U.S. Dollar =**

For all drugs recommended for purchase by the health worker, write the following information.

Name, Strength, and Dosage Form	Dosage Quantity	Frequency	Duration of Treatment (Days)	Mode of Administration	Price	Full Course Prescribed (Yes, No, N/A)
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7
Row 1: Did dispenser provide some information on how to take the medicines? YES NO						
Row 2: Did the dispenser prescribe medicines in line with STGs? YES NO						
Row 3: Total cost of prescribed treatment (total of column 6)						
Row 4: STG cost						
Row 5: % of STG cost (Row 4 ÷ Row 3)						

ANNEX 2. DATA COLLECTION TEAMS

Borno State
Mr. Odujoko
Mr. M. A. Aro
State RBM Program Manager
Pharmacist 1
Pharmacist 2

Cross River State
Dr. Ogori Taylor
Mrs. B. Momoh
Glory Opusunji
State RBM Program Manager
Pharmacist 1
Pharmacist 2

Kano State
Dr. J. Ugwu
S. O. Banjo
State RBM Program Manager
Pharmacist 1
Pharmacist 2

Lagos State
Dr. E. O. Nwokolo
Ajaegbu Nneka
State RBM Program Manager
Pharmacist 1
Pharmacist 2